being unpatentable over Shields in view of Goepp. Claims 8-9, 12-17, 21-25,27, 41-43 and 47-48 are rejected as being unpatentable over Lipfert in view of Shields and Goepp. Claims 52-56 and 59 are rejected as being unpatentable over Lipfert in view of Goepp and Koch '436. These rejections are respectfully traversed.

Even if each of the elements of Applicant's claimed invention is suggested in the cited references, which is not conceded, this does not in itself render the claimed invention unpatentable. As explained by the court in *The Gillette Co. v. S.C. Johnson & Son*:

> It is true that [the claimed invention] consists of a combination of old elements so arranged as to perform certain related functions. It is immaterial to the issue, however, that all of the elements were old in other contexts. *What must be found obvious to defeat the patent is the claimed combination.*
>
> Focusing on the obviousness of substitutions and differences, instead of the invention as a whole, is a legally improper way to simplify the often difficult determination of obviousness. (*The Gillette Co. v. S.C. Johnson & Son,* 919 F.2d 720, 724 (emphasis in original, citations omitted).)

Applicant submits that the claimed invention as a whole -- a cervical cap including, in combination with other claimed features, a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix-- is patentable over the references cited by the Examiner.

Under the standard articulated in *Graham v. John Deere Co.*, 383 U.S.1, 148 U.S.P.Q. 459 (1966), secondary considerations, such as a long felt but unresolved need prior to the claimed invention, must be considered in determining obviousness.

In this case, there has long been a grievous need for an improved female barrier contraceptive. The existing female barrier contraceptive devices at the time of the invention, i.e., diaphragms, Today Sponges, the Reality™ Condom, and cervical caps, are intrusive and are difficult to use effectively. Moreover, these devices can only be kept in place for short periods of time, increasing inconvenience and the likelihood that the device will not be used or will be used improperly. As a result, when pregnancies due to user failure are included, all of these barrier devices have at least a 15-20% pregnancy rate per year (the Reality condom has a rate of 27%). (Declaration of James P. Koch, submitted herewith, paragraph 2.)

In the United States, at the time of Applicant's invention only a single cervical cap -- the Prentif cap -- was FDA approved for clinical use. This cap can only be left in place for a maximum of 48 hours, causing inconvenience and a high user failure rate (17%). (Declaration of James P. Koch, paragraph 3.)

While these problems have been long recognized, women have long sought a reliable, safe alternative to oral contraceptives, and cervical cap technology has long existed, the need for an improved cervical cap remained unresolved prior to the claimed invention. Attempts had been made to improve cervical cap technology, but none of these attempts made it to the consumer. For example, while the Goepp cap is custom-molded, and thus can be kept in place for long periods of time, clinical trials showed that this cap did not provide adequate protection against pregnancy. (Declaration of James P. Koch, paragraph 4.)

The claimed invention meets this long felt but unresolved need by providing an improved female barrier contraceptive. Because the cap dome is custom-molded to substantially completely conform to the shape of the patient's cervix, the claimed cervical caps can be left in place for long periods of time, reducing the user failure rate attributable to improper insertion and removal. Because the cap can be left in place for long periods of time, it is also significantly less intrusive and more convenient to use than other female barrier devices. By including a valve, as recited in claims 1-16, the cap can be kept in place even during the patient's menstrual cycle. (Declaration of James P. Koch, paragraph 5.)

Because the claimed caps include a rim member dimensioned to fit the patient's exocervix, the claimed cervical caps also provide a secure seal to prevent ingress of semen and other fluids into the cervix, thus providing reliable protection against both pregnancy and sexually transmitted diseases (STDs). (Declaration of James P. Koch, paragraph 6.)

As a result of both the improved ease of use and the secure seal, the claimed cervical caps are expected to provide pregnancy rates much lower than those observed for conventional female barrier methods, making them a viable alternative to oral contraceptives. (Declaration of James P. Koch, paragraph 7.)

We submit that these considerations weigh overwhelmingly in favor of patentability.

Conclusion

In view of the above, Applicant respectfully requests that the rejections under 35 U.S.C. § 103 be withdrawn.

Attached is a marked-up version of the changes being made by the current amendment.

Applicant asks that all claims be allowed. Enclosed is a $55.00 check for the Petition for Extension of Time fee. It is believed that a one month extension fee is sufficient because the applicant's notice of appeal was received by the USPTO on October 23, 2002. However should a further 1 month extension be needed applicants authorize the PTO to charge the extension fee to applicant's Deposit Account. Please apply any other charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: January 23, 2003

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Version with markings to show changes made

In the claims:

Claim 51-56 have been cancelled without prejudice.

Claim 17 has been amended as follows:

17. A cervical cap comprising (a) a cap body that is constructed to cover the exocervix and prevent ingress of sperm and fluids and includes a cap dome that is custom-molded to substantially completely conform to the shape of the patient's cervix, (b) a rim member, dimensioned to fit a patient's exocervix, from which the cap body extends, and ([b]c) a portion, associated with the cap body, that is impregnated or coated with a therapeutic agent and is constructed to release the therapeutic agent over a period of time during use of the cap.